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United States Department of Agriculture Animal and Plant Health Inspection Service Center for Veterinary Biologics P. O. Box 844 Ames, IA 50010

1. Reagent Name: Clostridium botulinum Type C Antitoxin

2. Strain or Source: Not applicable

3. Lot Number: IRP 428

4. Fill Date: April 10, 1995

Expiration Date: No expiration date has been assigned to this product because *C. botulinum* type C antitoxin has demonstrated over time to be very stable if properly stored.

Precautions: There are no known hazards associated with the use of this reagent.

- **6. Intended Use:** To serve as the standard antitoxin when conducting *C. botulinum* type C toxin neutralization tests in mice.
- 7. Instructions for Use: Clostridium botulinum type C antitoxin IRP 428 contains 48 antitoxin units per mL (AU/mL). Dilutions of 1:1200, 1:2400, 1:4800, and 1:9600 contain 0.04 AU/mL, 0.02 AU/mL, 0.01 AU/mL, and 0.005 AU/mL, respectively. One and five-tenths mL of each dilution mixed with 1.5 mL of *C. botulinum* type C toxin IRP 421 diluted 1:40,000 provides results in which one group of mice all live and one group of mice all die when mice are injected intraperitoneally with 0.5 mL of the mixture.

8. Test of Reagent:

Determination of antitoxin titer — The antitoxin titer was determined by injecting mice in the intraperitoneal cavity with 0.5 mL of diluted antitoxin mixed with a known amount of *C. botulinum* type C toxin. The antitoxin titer was confirmed by comparing the results of mice injected with toxin-antitoxin mixtures containing IRP 428 with toxin-antitoxin mixtures containing *C. botulinum* type C International antitoxin.

Sterility test – Four vials of IRP 428 were tested for sterility by inoculating the antitoxin in tubes of sterile fluid thioglycollate medium and soybean-casein digest medium. No detectable growth appeared in any tubes of medium.

9. Container Size, Type, Weight, or Volume: Two-mL glass vials with 1.2 mL of antitoxin.

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- **10. Storage Conditions:** Store at -20°C or lower. Antitoxin that has been thawed should be stored at 2°- 7°C. Repeated freezing and thawing is not recommended.
- **11. CVB Technical Contact:** Bacteriology Section, Center for Veterinary Biologics, (515) 337-6100.
- **12. Origin and Passage History:** The serum was obtained from young adult goats immunized with antigen prepared from *C. botulinum* type C culture 203A (African strain).
- 13. Method of Preparation: The antitoxin was produced by vaccinating goats with *C. botulinum* type C toxoid, followed by a series of injections with *C. botulinum* type C toxin. Serum obtained from the goats was precipitated with ammonium sulfate and the dissolved precipitate dialyzed against 0.01 M PBS. The dialyzed material was passed through a sterile Millipore filter unit with a 0.22-µm membrane. No preservatives were added to the antitoxin.

14. Other: None

Reagent orders and feedback should be sent *including phone number* to the following email address: <u>VS.DB.CVB.Reagent.Requests@usda.gov</u>

Reagent orders forms (APHIS Form 2018) can be found on the CVB website.

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